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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/696,725

10/29/2003

Jeffrey M. Sieracki

1023-227US01

6322

28863

7590

12/05/2006

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EXAMINER

KAHELIN, MICHAEL WILLIAM

ART UNIT

PAPER NUMBER

3762

DATE MAILED: 12/05/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/696,725

Applicant(s)

SIERACKI ET AL.

Examiner

Michael Kahelin

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 August 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-41 is/are pending in the application.
- 4a) Of the above claim(s) 5-7, 15-17, 27 and 35-37 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-4, 8-14, 18-25, 28-34 and 38-41 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 29 October 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date 20060330;20040412.

- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Election/Restrictions

1. Claims 5-7, 15-17, 26, 27, 35-37, and 42-53 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 8/18/2006.
2. Applicant's election without traverse of claims 1-4, 8-14, 18-25, 28-34, and 38-41 in the reply filed on 8/18/2006 is acknowledged.

Information Disclosure Statement

3. The information disclosure statement filed 4/12/2004 fails to comply with the provisions of 37 CFR 1.97, 1.98 and MPEP § 609 because two of the references are within one year of the filing date of the instant application and lacking a publication month. It has been placed in the application file, but the information referred to therein has not been considered as to the merits. Applicant is advised that the date of any re-submission of any item of information contained in this information disclosure statement or the submission of any missing element(s) will be the date of submission for purposes of determining compliance with the requirements based on the time of filing the statement, including all certification requirements for statements under 37 CFR 1.97(e). See MPEP § 609.05(a).

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 1-4, 8, 10, 24, 25, 28-31, 33, 34, 38, and 39 are rejected under 35 U.S.C. 102(b) as being anticipated by Batty, Jr. et al. (US 4,550,732, hereinafter "Batty").

6. In regards to claim 1, 24 and 33, Batty discloses receiving stay-alive signals from a programmer, resetting a watchdog timer in response to receipt of stay-alive signals, and changing the mode of operation of the IMD in response to expiration of the watchdog timer (col. 2, line 49).

7. In regards to claims 2, 3 and 25, the signals are a PWM binary signal, which are transitions on a wireless telemetry data line (col. 2, line 49). Line is being interpreted in the sense of "a line of communication" wherein the line need not comprise a physical structure.

8. In regards to claims 4, 10, 29, 34 and 39, the IMD receives programming and stay-alive signals (col. 2, line 46) that reset/initialize the watchdog timer (col. 2, line 56). Because the mode change is initiated by a lack of activity over a predetermined period of time, activity will reset the timer that determines the lack of activity.

9. In regards to claims 8, 28, and 38, changing the mode of operation comprises reverting to a previously stored program (col. 6, line 63).

10. In regards to claims 30 and 31, the watchdog unit comprises a processor that further controls the operation of the IMD (32).

Claim Rejections - 35 USC § 103

11. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

12. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

13. Claims 11, 12, 32, 40, and 41 are rejected under 35 U.S.C. 103(a) as being unpatentable over Batty. Batty discloses the essential features of the claimed invention except for changing the mode of operation based on an emergency-off from the user; utilizing the watchdog system in a neurostimulator; or detecting power delivery failure, activating auxiliary power, and changing the mode of operation in response to the detection. It is well known in the art to change a mode of operation based on an

emergency-off from a user to allow a patient to suspend therapy based on a physiological condition or device malfunction; to utilize telemetry features, such as watchdog timers, in neurostimulators to provide easy and reliable communication with these implanted devices; and to detect power delivery failure, activate auxiliary power, and change the mode of operation in response to the detection to provide an implantable device with a constant source of power. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify Batty's invention by changing a mode of operation based on an emergency-off from a user to allow a patient to suspend therapy based on a physiological condition or device malfunction; to utilize the watchdog timer in neurostimulator to provide easy and reliable communication with these implanted devices; and to detect power delivery failure, activate auxiliary power, and change the mode of operation in response to the detection to provide an implantable device with a constant source of power.

14. Claims 9, 13, 14 and 18-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Batty in view of Grevious et al. (US 5,752,977, hereinafter "Grevious"). Batty discloses the essential features of the claimed invention except for changing the mode of operation by sending a signal to the implantable device via telemetry. Grevious teaches of instructing an IMD to change a mode of operation via telemetry in the event that an error is detected (col. 11, line 41) to ensure that the IMD provides suitable therapy in spite a faulty telemetry transmission. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify Batty's invention by instructing the IMD to change a mode of operation

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via telemetry in the event that an error is detected to ensure that the IMD provides suitable therapy in spite a faulty telemetry transmission.

15. In regards to claims 22 and 23, Batty and Grevious discloses the claimed invention but does not disclose expressly that the device is placed in a telemetry head or connected to a telemetry head by a cable. It would have been an obvious matter of design choice to a person of ordinary skill in the art to modify the error detection device as taught by Batty and Grevious with the claimed configuration because applicant has not disclosed that the claimed configurations provide an advantage, are used for a particular purpose, or solve a stated problem. One of ordinary skill in the art, furthermore, would have expected Applicant's invention to perform equally well with the device as taught by Batty and Grevious because both configurations will detect telemetry errors and initiate a fallback mode. Therefore, it would have been an obvious matter of design choice to further modify Batty's invention to obtain the invention as specified in the claims.

Conclusion

16. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Causey, III et al. (US 5,792,201) is one of many teachings of providing user-off input via telemetry and Schulman (US 3,942,535) is one of many teachings of detecting power delivery failure and changing the operation of an IMD accordingly.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Kahelin whose telephone number is (571) 272-8688. The examiner can normally be reached on M-F, 9-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on (571) 272-4955. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

MWK

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11/29/06

GEORGE R. EVANISKO
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PRIMARY EXAMINER

11/30/06